Remarks

Claims 1-30 are pending in the application and claims 1-27 and 30 are withdrawn from consideration. Applicants reserve the option to further prosecute the same or similar claims in the instant or in a subsequent patent application. Claim 27 has been amended, and new claims 31-47 have been added. No new matter has been added. Support for the amendments may be found throughout the specification, including the claims as originally filed. For example, support for amended claim 27 may be found at page 9, page 12, and pages 41-43 of the specification. In another example, support for new claim 31 may be found at pages 21-23, and in yet another example, support for new claims 36 and 38 may be found at pages 61-63 and Figures 4 and 5.

Amendment of claims should in no way be construed to narrow their scope or as an acquiescence to any of the Examiner's rejections. The amendments to the claims are being made solely to expedite prosecution of the present application. Applicants reserve the option to further prosecute the same or similar claims in the instant or in a subsequent patent application.

IDS

The Examiner has noted that documents EP and EU have not been considered because the listed documents do not have a publication date. Applicants thank the Examiner for alerting them to this deficiency and herewith provide the requested information.

EP refers to the International Search Report. The documents listed in the International Search Report were already submitted in the following Supplemental IDS filed as follows:

Reference	**IDS**	**Document Number**
Campbell, et al.	Supplemental IDS filed September 23, 2002	EL
Darst, et al. US6,225,076	Supplemental IDS filed September 23, 2002	EH
Naryshkina, et al.	Supplemental IDS filed September 23, 2002	EK
Cohen, et al.	Supplemental IDS filed September 23, 2002	EM
Mustaev, et al.	Supplemental IDS filed September 23, 2002	EI
Mustaev, et al.	Supplemental IDS filed September 23, 2002	EJ
Naryskin, et al.	Supplemental IDS filed September 23, 2002	EN
Zhang, et al.	Supplemental IDS filed November 6, 2002	EJ

Furthermore, the Examiner has pointed out that the date for document EU listed in Paper 14 is missing. The correct citation and publication date for document EU, Paper 14, is *Mol. Pharmacol.* 1983 Jan;23(1):133-40.

Rejection of claims 27-29 under Provisional Obvious-Type Double Patenting

Claims 27-29 were rejected for reasons of provisional obvious-type double patenting over claims 7 and 8 of U.S. Patent No. 6,225,076 to Darst, et al. Applicants respectfully traverse this rejection.

The analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. § 103 obviousness determination. In re Braat, 937 F.2d 589, 19 U.S.P.Q.2d 1289 (Fed. Cir. 1991); In re Longi, 759 F.2d 887, 225 U.S.P.Q. 645 (Fed. Cir. 1985). To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (CCPA 1970).

Claim 27 claims a method for identifying a compound predicted to inhibit bacterial growth by using certain atomic coordinates of the rifampicin-bound structure of RNA polymerase taught by the present application. Applicants respectfully assert that the Darst '076 patent does not disclose or suggest all of the claim limitations of claim 27, namely that certain of the atomic coordinates of the rifampicin-bound RNA polymerase be used in a method of identifying a predicted bacterial growth inhibitor. The Examiner has pointed out that although the claims of the Darst '076 patent "do not specify the atomic coordinates be derived from a rifampicin bound RNA polymerase, its specification discloses '[i]nitially, compounds known to bind bacterial RNA polymerase, for example rifampicin which binds to the .beta. subunit can be systematically modified by computer modeling programs until one or more promising potential analogs are identified.'" However, the Darst '076 patent does not disclose or suggest that the crystal structure of rifampicin-bound RNA polymerase be determined and that certain of the resultant coordinates be used in a method for identifying bacterial growth inhibitors. Therefore, Applicants respectfully urge that the Examiner has failed to make a *prima facie* case of obviousness, and request that the Examiner withdraw this rejection.

Rejection of claims 27-29 under 35 U.S.C § 103(a)

Claims 27-29 were rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 6,225,076 to Darst, et al. in view of In re Gulack, 703 F.2d 1381, 1385, 217 U.S.P.Q. 401,404 (Fed. Cir. 1983). The Examiner states that "[e]ven though the method disclosed by Darst, et al. does not specify that the atomic coordinates be derived from rifampicin bound to the core RNA polymerase (Rif-RNAP), the specific limitations of atomic coordinates of rifampicin bound to the core RNA polymerase in this instant case do not distinguish the invention from the prior art in term of patentability because they are descriptive nonfunctional subject matter."

The presence of the claimed nonfunctional descriptive material is not necessarily determinative of nonstatutory subject matter. (MPEP § 2106) For example, a computer that recognizes a particular grouping of musical notes read from memory and upon recognizing that particular sequence, causes another defined series of notes to be played, defines a functional interrelationship among that data and the computing processes performed when utilizing that data, and as such is statutory because it implements a statutory process. (*Id.*) Further, In re: Gulack states that when descriptive material is functionally related to the substrate, the descriptive material will distinguish the invention from the prior art in terms of patentability. Functional descriptive material is a limitation in the claim and must be considered and addressed in assessing patentability under 35 U.S.C. § 103. Thus, a rejection of the claim as a whole under 35 U.S.C. § 103 is inappropriate unless the functional descriptive material would have been suggested by the prior art. In re Dembiczak, 175 F.3d 994, 1000, 50 U.S.P.Q.2d 1614, 1618 (Fed. Cir. 1999).

Applicants assert that the structure of Rif-RNAP is functionally related to the process of claim 27 because the structure is necessary to implement the claimed method. In claim 27, the identifying step of the compound structure is performed by using the structure of Rif-RNAP or a portion thereof in rational drug design performed in conjunction with computer modeling. Because the structural information is used to identify another potential growth inhibitor, the structural information is functional in character. Hence, Applicants contend that the structural information may be used to distinguish the pending claims from the Darst '076 patent.

As discussed *supra*, the Darst '076 patent does not disclose or suggest that the atomic coordinates of the crystal structure of rifampicin-bound RNA polymerase be used in a method

for identifying a compound that is predicted to inhibit bacterial growth. Therefore, Applicants respectfully assert that the Examiner has failed to make a *prima facie* case of obviousness, and request reconsideration and withdrawal of this rejection.

Rejection of claims 27-29 under 35 U.S.C § 112, first paragraph

Claims 27-29 were rejected under 35 U.S.C. § 112, first paragraph, for reasons of lack of enablement. The Examiner states that: "the specification, while being enabling for a crystal core RNA polymerase with rifampicin which have atom coordinates instantly disclosed, does not reasonably provide enablement for a crystal of a portion of the core RNA polymerase with rifampicin." Further, the Examiner states that "[i]n light of the difficulty of the protein crystallization process, it is therefore unreasonable to expect one skilled in the art to use the information disclosed to use the information disclosed for one specific crystal to make others of predictable quality that are different from the crystal disclosed in the specification without undue experimentation."

The rejection is respectfully traversed. Applicants respectfully point the Examiner's attention to the language of claim 27, "defining the structure of rifampicin bound to the core RNA polymerase (Rif-RNAP) or a portion of the Rif-RNAP by the atomic coordinates in Table 2". A new crystal of a portion of Rif-RNP is not required by claim 27, rather, the structure is defined using the existing, already enabled, atomic coordinates in Table 2. Applicants respectfully request that the Examiner withdraw this rejection.

Conclusion

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-832-1000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this application be charged to Deposit Account, **No. 06-1448**.

Respectfully submitted,

Foley Hoag LLP

By: _____

Jennifer A. Zarutskie, Ph.D.
Reg. No. 50,558
Agent for Applicants

Patent Group
FOLEY HOAG LLP
155 Seaport Blvd.
Boston, MA 02210-2600
Telephone: (617) 832-1000
Facsimile: (617) 832-7000

Dated: May 29, 2003

Customer No. 25181